

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health

National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Summary Minutes

Date: September 24, 2001
Place: Building 31C, Conference Room 10
National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE
NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

September 24, 2001

The 166th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on September 24, 2001, at 10:00 a.m., in Building 31C, Conference Room 10, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 10:00 a.m. to 11:30 a.m., followed by the closed session for consideration of grant applications from 11:30 a.m. until adjournment at 12:30 p.m. Dr. Lawrence A. Tabak presided as Chair.

Members Present:

Dr. D. Walter Cohen

Members Present by Teleconference:

Dr. Samuel F. Dworkin
Dr. Raymond Fonseca
Dr. Jay Alan Gershen
Dr. Howard K. Kuramitsu
Dr. Harold Morris
Dr. Linda C. Niessen
Dr. Leslie Raulin
Dr. Dianne E. Rekow
Dr. Martha J. Somerman
Ms. Kim S. Uhrich

Members of the Public Present:

Dr. Aida Chohayeb, Professor, Howard University, Washington, DC
Ms. Julie Scott, American Dental Association, Washington, DC

Members of the Public by Teleconference:

Mr. Jonathan Schuermann, University of Missouri, Columbia, MO
Ms. Nina Shehzad, "Blue Sheet," Chevy Chase, MD

Federal Employees Present:

National Institute of Dental and Craniofacial Research:

Dr. Margo Adesanya, Senior Scientist, Craniofacial Epidemiology and Genetics Branch, Office of Science Policy and Analysis (OSPA)
Ms. Carolyn Baum, Committee Management Specialist and Council Secretary, Office of the Director (OD)
Dr. Norman S. Braveman, Associate Director, Office of Clinical, Behavioral, and Health Promotion Research, Division of Extramural Research (DER)
Dr. Patricia S. Bryant, Health Scientist Administrator, Behavioral and Health Promotion Research, DER
Ms. Maria Teresa Canto, Public Health Research Specialist, OSPA
Dr. Lois Cohen, Director, Office of International Health (OIH)

Mr. George J. Coy, Chief, Office of Administrative Management (OAM)
Ms. Yvonne du Buy, Executive Officer, OAM
Mr. William Foley, Grants Management Specialist, DER
Dr. Isabel Garcia, Public Health Officer, OD
Ms. Christen Gibbons, Computer Specialist, Office of Information Technology (OIT)
Dr. Kevin Hardwick, International Health Officer, OIH
Ms. Lorraine Jackson, Diversity Programs Specialist, and Co-Director, Diversity Programs, DER
Mr. William M. Johnston, Consultant, Biomaterials, Biomimetics, and Tissue Engineering Branch, DER
Dr. Dushanka V. Kleinman, Deputy Director, NIDCR, and Executive Secretary, NADCRC
Dr. Eleni Kousvelari, Chief, Biomaterials, Biomimetics, and Tissue Engineering Branch, DER
Ms. Wendy A. Liffers, Director, OSPA
Dr. James A. Lipton, Assistant Director, Office of Training and Career Development, DER
Dr. Yujing Liu, Scientific Review Administrator, DER
Ms. Carol Loose, Budget Analyst, OAM
Dr. Dennis F. Mangan, Chief, Infectious Diseases and Immunity Branch, DER
Dr. J. Ricardo Martinez, Associate Director for Program Development, OD
Dr. Ruth Nowjack-Raymer, Public Health Research Specialist, OSPA
Dr. Martin Rubinstein, Chief, Grants Management Branch, DER
Dr. Ann L. Sandberg, Chief, Neoplastic Diseases Branch, and Director, Comprehensive Centers of Discovery Program, DER
Dr. Yasaman Shirazi, Scientific Review Administrator, DER
Dr. Rochelle Small, Chief, Craniofacial Anomalies and Injuries Branch, DER
Ms. Tracy Walker, Secretary, OSPA
Ms. Mary Ann Williamson, Computer Specialist, OIT
Dr. Guo H. Zhang, Health Scientist Administrator, DER
Ms. Amy Zukowski, Budget Analyst, OAM

OPEN PORTION OF THE MEETING

I. CALL TO ORDER

Dr. Lawrence Tabak called the meeting to order. He polled the Council members attending by teleconference and welcomed all attendees. Dr. Tabak asked the staff sitting at the Council table and other attendees to introduce themselves. Dr. Tabak instructed the teleconference members on the procedures for the meeting.

II. REPORT OF THE DIRECTOR

Dr. Tabak highlighted portions of the Director's Report (report attached) and mentioned that portions of the planned meeting on clinical research would be handled by selected Council members organized as a small committee and that additional discussion of this topic would be held at the January 2002 Council meeting.

III. CONCEPT CLEARANCES

Dr. Tabak presented four concepts for the Council's consideration.

Temporomandibular Joint Implant Patient Registry

The Institute proposes to issue a Request for Proposals (RFP) to establish and maintain a national registry of patients who have had or will receive implants for the temporomandibular joint (TMJ). Additional goals for this initiative are to: collect medical information on enrollees; to document the state of the TMJ in patients before and after removal

of the implant; to retrieve and maintain TMJ implants from patients; to correlate the condition of retrieved implants with the medical state of patients; and to develop a process for making TMJ implants available to biomedical researchers studying the performance of medical implants. The natural history of TMJ implants has not been investigated systematically, and long-term data are essential for determining the feasibility of implants. The registry would serve as a national resource for biomedical researchers seeking to understand the natural history of TMJ implants and to improve their performance.

About 3 to 5 percent of Americans, mostly women, are affected by temporomandibular disorders (TMD), and an estimated 100,000 patients have received one or more TMJ devices. Over the past 15 years, the failure of TMJ implants has been reported numerous times in the scientific literature, and public hearings on the consequences of these failures have drawn considerable publicity. In January 2000, the NIH held a technology assessment conference on "Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities," which highlighted the importance of retrieving and analyzing implants and the need for a patient registry. A subsequent meeting of the Food and Drug Administration (FDA) Dental Products Panel noted the paucity of data on the natural history of TMD.

The NIDCR is the lead NIH institute for research on TMD, but currently supports little extramural activity in the critical areas proposed for the Broad Agency Announcement (BAA). Retrieval and analysis of TMJ implants is essential for improving the care of patients who may need implants. The BAA would be developed based on the recommendations from the NIH technology assessment conference (available at http://odp.od.nih.gov/consensus/ta/-109/019_statement.htm). The FDA and the NIH Office of Research on Women's Health (ORWH) have expressed interest in cosponsoring the initiative.

The Council enthusiastically supported the concept, noting that this initiative would have tremendous value for both patients and researchers. Members commented on several aspects pertaining to the construction and activities of the proposed registry. Staff noted that utilization of the contract mechanism to support this initiative will enable NIDCR to ensure that certain specifications mentioned by the Council are included (e.g., evaluation of oral health status, assessment of the natural history of TMD in patients who do not receive implants, participation of oral surgeons in identifying and retrieving relevant cases, collection of data on the diagnosis and biomedical rationale for providing implants, and measurements of quality of life before and active treatment).

The Council unanimously approved the concept.

International Research Registries for Sjögren's Syndrome

The Institute proposes to issue an RFP to establish uniformly accepted diagnostic criteria for primary and secondary Sjögren's syndrome, which would be used by all countries for all research purposes, and one or more research registries for families with Sjögren's syndrome residing in the United States, Europe, Asia, and the Pacific. The NIDCR envisions that the registries would serve as a national and international resource that would promote and facilitate basic and clinical research on Sjögren's syndrome. The registries would provide for standardization of methods for collecting, maintaining, storing, analyzing, and processing patients' information and biological specimens; storage of clinical data from well-characterized patient populations and specimens; data on the prevalence of the disorder in the general population and in population subgroups; enhancement of genetic studies; clarification of the clinical characteristics of the disorder; characterization of influential genetic mutations or gene interactions; measurement and analysis of pathological parameters; evaluation of the efficacy of current therapies; and testing of novel therapeutic strategies.

The prevalence of Sjögren's syndrome in the general population is not clear because existing diagnostic criteria (e.g., in the United States, Europe, Japan) are not uniformly accepted or standardized. Diagnosis and its influence on treatment and prevention are additionally compromised by the complex and controversial etiology and the pathogenesis of the syndrome. Current treatment is palliative only. The NIDCR has held two workshops pertinent to Sjögren's syndrome. The first, in November 1996, was on "Salivary Gland Biogenesis and Function," and the second, in September 2000, focused on "Enhancing Clinical Research in Sjögren's Syndrome: Critical Issues."

The NIDCR is the lead NIH institute in research on Sjögren's syndrome, but the extramural program supports only a few studies on the pathogenesis of this disorder. The RFP would be developed based on the recommendations from the two workshops. Having a resource of patient information and specimens will greatly accelerate research on this disorder and potentially attract investigators from other fields of study. The ORWH, the National Institute of Arthritis and Musculoskeletal Diseases, and the National Eye Institute have expressed interest in supporting the initiative.

The Council noted the need, for comparison, to also identify and follow the natural history of Sjögren's syndrome in patients who refuse treatment.

The Council unanimously approved the concept.

Developmental Grants to Reduce Oral Health Disparities

The NIDCR proposes to issue a Request for Applications (RFA) for planning and pilot investigations that address the diseases, conditions, and common risk/health factors of population groups suffering oral health disparities. Health disparities are defined as the diminished health status of population groups based on demographic factors such as age and socioeconomic status, geography, disability, and behavioral lifestyles. These factors reflect the diversity of the U.S. population as defined by gender, age, racial or ethnic identity, educational attainment, and income. The initiative, which will be cofunded with the National Center for Minority Health and Health Disparities (NCMHHD), will focus on populations and areas that have not been addressed fully in the current NIDCR portfolio, but are highlighted in NIDCR's strategic Plan to Eliminate Craniofacial, Oral, and Dental Health Disparities (available at <http://www.nidcr.nih.gov>).

As highlighted in the U.S. Surgeon General's Report *Oral Health in America*, particular population groups suffer disproportionately higher burdens of disease in the United States. The NIDCR developed its strategic plan in response to the findings presented in this report and has focused its resources on eliminating disparities in craniofacial, oral, and dental health. The establishment and funding of NIDCR Centers for Research to Reduce Oral Health Disparities (CRROHDs) is one action step in this plan. The proposed RFA would augment this and other NIDCR actions by fostering research in areas that are *not* being addressed and by helping institutions enhance their capacity for this research. Emphasis would be given to studies of health disparities in U.S. population groups that are not being addressed or only slightly addressed in the NIDCR research portfolio (i.e., Appalachian, Hispanic, Native American, and Asian Pacific Islander populations, and groups with low socioeconomic status).

The awards will utilize the R-21 mechanism. The NIDCR anticipates that awardees would subsequently submit successful applications to obtain an R01 award or an investigator-initiated interactive research project grant (IRPG).

The Council applauded the NIDCR on developing this and the following initiative and for continuing to work closely with the ORMHHD. Staff noted that the initiative will complement the CRROHDs by focusing on additional specific population groups and on minority institutions as the primary site of research.

The Council unanimously approved the concept.

Infrastructure and Capacity Building for Minority Institutions to Reduce Oral Health Disparities

The NIDCR proposes to collaborate with the NCMHHD to provide funding to minority-serving dental schools (institutions) (i.e., Howard University, Meharry College, and the University of Puerto Rico) for infrastructure and capacity building in research and research training. The resources would be used for the development and implementation of institutional plans to establish an infrastructure for research; recruit and retain personnel with research expertise; establish linkages with dental, oral, and craniofacial research-intensive institutions; and conduct research to eliminate oral health disparities.

Oral and craniofacial diseases and disorders are among the most common health problems affecting the U.S. population, and particular subgroups have a disproportionately higher burden of these problems. Addressing the

disparities in craniofacial, oral, and dental health among diverse populations in the United States continues to be a major focus of NIDCR research. Minority-serving dental schools and institutions have a rich source of talent with the cultural sensitivity and perspective needed for this research, but have not developed and sustained a critical mass of researchers in craniofacial, oral, and dental research.

The proposed funding would be provided to the schools or institutions in two phases within a 3-year cooperative agreement. The institution's plan would be developed during the first phase and implemented during the second phase. By the end of the 3-year period, the schools or institutions would be expected to have strengthened their capacity for research on oral health disparities and be able to submit scientifically meritorious developmental grant applications and to initiate relevant training and career development programs.

The Council emphasized the need for collaborations and partnerships across institutions and with other Federal agencies and professional organizations to accomplish the goals of the initiative. Members expressed concern about the duration and resources for phase II, suggesting that the Institute reconsider the scope given the proposed timeframe. It was noted that evaluation of previous NIDCR efforts to link research-intensive institutions with nonresearch-intensive schools would be informative.

The Council unanimously approved the concept.

CLOSED PORTION OF THE MEETING

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

There was a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves or were blocked by a standby teleconference operator from the meeting during discussion of, and voting on, applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

IV. REVIEW OF APPLICATIONS

Grant Review

The Council considered 297 applications requesting \$ 62,464,164 in total costs. The Council recommended 241 applications for a total cost of \$ 51,364,263 (see Attachment II).

ADJOURNMENT

The meeting was adjourned at 12:30 p.m. on September 24, 2001.

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

Dr. Lawrence A. Tabak
Chairperson
National Advisory Dental and
Craniofacial Research Council

Dr. Dushanka V. Kleinman
Executive Secretary
National Advisory Dental and
and Craniofacial Research Council

ATTACHMENTS

- I. Roster of Council Members
- II. Table of Council Actions
- III. Report of the Director

NOTE: A complete set of open-portion handouts are available
from the Executive Secretary.